

Senate Bill No. 585

Passed the Senate May 17, 1999

Secretary of the Senate

Passed the Assembly June 24, 1999

Chief Clerk of the Assembly

This bill was received by the Governor this _____ day
of _____, 1999, at _____ o'clock ____M.

Private Secretary of the Governor

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CHAPTER _____

An act to amend Sections 1206.5, 1265, and 1300 of the Business and Professions Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

SB 585, Chesbro. Clinical laboratories.

Existing law provides that clinical laboratory examinations classified as physician-performed microscopy under specified federal regulations governing clinical laboratories may be performed by licensed physicians and surgeons, as specified.

This bill would expand that category of persons who may perform those clinical laboratory examinations to include licensed nurse practitioners, licensed physician assistants, certified nurse midwives, and licensed dentists. The bill would also make technical changes.

The people of the State of California do enact as follows:

SECTION 1. Section 1206.5 of the Business and Professions Code is amended to read:

1206.5. (a) Notwithstanding subdivision (b) of Section 1206, no person shall perform a clinical laboratory test or examination classified as waived under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

(1) A licensed physician and surgeon holding a M.D. or D.O. degree.

(2) A licensed podiatrist or a licensed dentist when the results of the tests can be lawfully utilized within his or her practice.



(3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.

(4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.

(5) A licensed physician assistant when authorized by a supervising physician and surgeon in accordance with Section 3502 or Section 3535.

(6) A person licensed under Chapter 6 (commencing with Section 2700).

(7) A person licensed under Chapter 6.5 (commencing with Section 2840).

(8) A perfusionist when authorized by and performed in compliance with Section 2590.

(9) A respiratory care practitioner when authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).

(10) A medical assistant, as defined in Section 2069, when the waived test is performed pursuant to a specific authorization meeting the requirements of Section 2069.

(11) A pharmacist, when ordering drug therapy-related laboratory tests in compliance with clause (ii) of subparagraph (A) of paragraph (5) of subdivision (a) of, or paragraph (6) of subdivision (a) of, Section 4052.

(12) Other health care personnel providing direct patient care.

(b) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of moderate complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:



(1) A licensed physician and surgeon holding a M.D. or D.O. degree.

(2) A licensed podiatrist or a licensed dentist when the results of the tests can be lawfully utilized within his or her practice.

(3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.

(4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.

(5) A licensed physician assistant when authorized by a supervising physician and surgeon in accordance with Section 3502 or Section 3535.

(6) A person licensed under Chapter 6 (commencing with Section 2700).

(7) A perfusionist when authorized by and performed in compliance with Section 2590.

(8) A respiratory care practitioner when authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).

(9) A person performing nuclear medicine technology when authorized by and performed in compliance with Article 6 (commencing with Section 107115) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.

(10) Any person when performing blood gas analysis in compliance with Section 1245.

(11) (A) A person certified as an “Emergency Medical Technician II” or paramedic pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code while providing prehospital medical care, a person licensed as a psychiatric technician under Chapter 10 (commencing with Section 4500) of Division 2, as a vocational nurse pursuant to Chapter 6.5 (commencing with Section 2840) of Division 2, or as a midwife licensed pursuant to Article 24 (commencing with Section 2505) of Chapter 5 of Division 2, or certified by the department pursuant to Division 5 (commencing with Section 70001) of Title 22 of the California Code of



Regulations as a nurse assistant or a home health aide, who provides direct patient care, so long as the person is performing the test as an adjunct to the provision of direct patient care by the person, is utilizing a point-of-care laboratory testing device at a site for which a laboratory license or registration has been issued, meets the minimum clinical laboratory education, training, and experience requirements set forth in regulations adopted by the department, and has demonstrated to the satisfaction of the laboratory director that he or she is competent in the operation of the point-of-care laboratory testing device for each analyte to be reported.

(B) Prior to being authorized by the laboratory director to perform laboratory tests or examinations, testing personnel identified in subparagraph (A) shall participate in a preceptor program until they are able to perform the clinical laboratory tests or examinations authorized in this section with results that are deemed accurate and skills that are deemed competent by the preceptor. For the purposes of this section, a “preceptor program” means an organized system that meets regulatory requirements in which a preceptor provides and documents personal observation and critical evaluation, including review of accuracy, reliability, and validity, of laboratory testing performed.

(12) Any other person within a physician office laboratory when the test is performed under the supervision of the patient’s physician and surgeon or podiatrist who shall be accessible to the laboratory to provide onsite, telephone, or electronic consultation as needed, and shall: (A) ensure that the person is performing test methods as required for accurate and reliable tests; and (B) have personal knowledge of the results of the clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.

(13) A pharmacist, when ordering drug therapy-related laboratory tests in compliance with clause (ii) of subparagraph (A) of paragraph (5) of



subdivision (a) of, or paragraph (6) of subdivision (a) of, Section 4052.

(c) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of high complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

(1) A licensed physician and surgeon holding a M.D. or D.O. degree.

(2) A licensed podiatrist or a licensed dentist when the results of the tests can be lawfully utilized within his or her practice.

(3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory when the test or examination is within a specialty or subspecialty authorized by the person's licensure.

(4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code when the test or examination is within a specialty or subspecialty authorized by the person's certification.

(5) A licensed physician assistant when authorized by a supervising physician and surgeon in accordance with Section 3502 or Section 3535.

(6) A perfusionist when authorized by and performed in compliance with Section 2590.

(7) A respiratory care practitioner when authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).

(8) A person performing nuclear medicine technology when authorized by and performed in compliance with



Article 6 (commencing with Section 107115) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.

(9) Any person when performing blood gas analysis in compliance with Section 1245.

(10) Any other person within a physician office laboratory when the test is performed under the onsite supervision of the patient's physician and surgeon or podiatrist who shall: (A) ensure that the person is performing test methods as required for accurate and reliable tests; and (B) have personal knowledge of the results of clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.

(d) Clinical laboratory examinations classified as provider-performed microscopy under CLIA may be personally performed using a brightfield or phase/contrast microscope by one of the following practitioners:

(1) A licensed physician and surgeon using the microscope during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or employee.

(2) A nurse midwife holding a certificate as specified by Section 2746.5, a licensed nurse practitioner as specified in Section 2835.5, or a licensed physician assistant acting under the supervision of a physician pursuant to Section 3502 using the microscope during the patient's visit on a specimen obtained from his or her own patient or from the patient of a clinic, group medical practice, or other health care provider of which the certified nurse midwife, licensed nurse practitioner, or licensed physician assistant is an employee.

(3) A licensed dentist using the microscope during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee.

SEC. 2. Section 1265 of the Business and Professions Code is amended to read:

1265. (a) (1) A clinical laboratory performing clinical laboratory tests or examinations classified as of moderate or of high complexity under CLIA shall obtain a clinical laboratory license pursuant to this chapter. The department shall issue a clinical laboratory license to any person who has applied for the license on forms provided by the department and who is found to be in compliance with this chapter and the regulations pertaining thereto. No clinical laboratory license shall be issued by the department unless the clinical laboratory and its personnel meet the CLIA requirements for laboratories performing tests or examinations classified as of moderate or high complexity, or both.

(2) A clinical laboratory performing clinical laboratory tests or examinations subject to a certificate of waiver or a certificate of provider-performed microscopy under CLIA, shall register with the department. The department shall issue a clinical laboratory registration to any person who has applied for the registration on forms provided by the department and is found to be in compliance with this chapter, the regulations pertaining thereto, and the CLIA requirements for either a certificate of waiver or a certificate of provider-performed microscopy.

(b) An application for a clinical laboratory license or registration shall include the name or names of the owner or the owners, the name or names of the laboratory director or directors, the name and location of the laboratory, a list of the clinical laboratory tests or examinations performed by the laboratory by name and total number of test procedures and examinations performed annually (excluding tests the laboratory may run for quality control, quality assurance, or proficiency testing purposes). The application shall also include a list of the tests and the test kits, methodologies, and laboratory equipment used, and the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures, and any other relevant information as may



be required by the department. If the laboratory is performing tests subject to a provider-performed microscopy certificate, the name of the provider or providers performing those tests shall be included on the application. Application shall be made by the owners of the laboratory and the laboratory directors prior to its opening. A license or registration to conduct a clinical laboratory if the owners are not the laboratory directors shall be issued jointly to the owners and the laboratory directors and the license or registration shall include any information as may be required by the department. The owners and laboratory directors shall be severally and jointly responsible to the department for the maintenance and conduct thereof or for any violations of this chapter and regulations pertaining thereto.

(c) The department shall not issue a license or registration until it is satisfied that the clinical laboratory will be operated within the spirit and intent of this chapter, that the owners and laboratory directors are each of good moral character, and that the granting of the license will not be in conflict with the interests of public health.

(d) A separate license or registration shall be obtained for each laboratory location, with the following exceptions:

(1) Laboratories that are not at a fixed location, that is, laboratories that move from one testing site to another, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations, may apply for and obtain one license or registration for the designated primary site or home base, using the address of that primary site.

(2) Not-for-profit, or federal, state, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests, as defined under CLIA, per license) public health testing may apply for and obtain a single license or registration.

(3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under



common direction, may file a single application or multiple applications for a license or registration of laboratory locations within the same campus or street address.

(4) Locations within a single street and city address that are under common ownership may apply for and obtain a single license or registration or multiple licenses or registrations, at the discretion of the owner or owners.

(e) A license or registration shall be automatically revoked in 30 days if there is a major change of laboratory directorship or ownership. The license or registration shall be valid for the calendar year or remainder thereof for which it is issued unless revoked or suspended. If the department does not within 60 days after the date of receipt of the application issue a license or registration, it shall state the grounds and reasons for its refusal in writing, serving a copy upon the applicant by certified mail addressed to the applicant at his or her last known address.

(f) The department shall be notified within 30 days of any change in ownership, name, location, or laboratory directors.

SEC. 3. Section 1300 of the Business and Professions Code is amended to read:

1300. The amount of application, registration, and license fees under this chapter shall be as follows:

(a) The application fee for a histocompatibility laboratory director's, clinical laboratory bioanalyst's, clinical chemist's, clinical microbiologist's, clinical laboratory toxicologist's, clinical cytogeneticist's, or clinical molecular biologist's license is thirty-eight dollars (\$38). This fee shall be sixty-three dollars (\$63) commencing on July 1, 1983.

(b) The annual renewal fee for a histocompatibility laboratory director's, clinical laboratory bioanalyst's, clinical chemist's, clinical microbiologist's, or clinical laboratory toxicologist's license is thirty-eight dollars (\$38). This fee shall be sixty-three dollars (\$63) commencing on July 1, 1983.



(c) The application fee for a clinical laboratory scientist's or limited clinical laboratory scientist's license is twenty-three dollars (\$23). This fee shall be thirty-eight dollars (\$38) commencing on July 1, 1983.

(d) The application and annual renewal fee for a cytotechnologist's license shall be fifty dollars (\$50) commencing on January 1, 1991.

(e) The annual renewal fee for a clinical laboratory scientist's or limited clinical laboratory scientist's license is fifteen dollars (\$15). This fee shall be twenty-five dollars (\$25) commencing on July 1, 1983.

(f) The application fee for a clinical laboratory license is six hundred dollars (\$600).

(g) The annual renewal fee for a clinical laboratory license is five hundred fifty-seven dollars (\$557).

(h) The application fee for a certificate of accreditation issued pursuant to Section 1223 is one hundred fifty dollars (\$150).

(i) The annual renewal fee for a certificate of accreditation issued pursuant to Section 1223 is one hundred dollars (\$100).

(j) In addition, clinical laboratories providing cytology services shall pay an annual fee that shall be set by the department in an amount needed to meet but not exceed the department's costs of proficiency testing and special site surveys for these laboratories, and that shall be based upon the volume of cytologic slides examined by a laboratory. If the amount collected is less than or exceeds the amount needed for these purposes, the amount of fees collected from those laboratories in the following year shall be adjusted accordingly.

(k) The application fee for a trainee's license is eight dollars (\$8). This fee shall be thirteen dollars (\$13) commencing on July 1, 1983.

(l) The annual renewal fee for a trainee's license is five dollars (\$5). This fee shall be eight dollars (\$8) commencing on July 1, 1983.

(m) The application fee for a duplicate license is three dollars (\$3). This fee shall be five dollars (\$5) commencing on July 1, 1983.

(n) The delinquency fee is equal to the annual renewal fee.

(o) The director may establish a fee for examinations required under this chapter. The fee shall not exceed the total cost to the department in conducting the examination.

(p) The certification and renewal fees for hemodialysis technicians certified under subdivision (a) of Section 1247.6 shall be fifty dollars (\$50). This subdivision shall become inoperative on July 1, 2000, and shall have no effect after that date.

(q) The annual fee for a clinical laboratory subject to registration under paragraph (2) of subdivision (a) of Section 1265 and performing only those clinical laboratory tests or examinations considered waived under CLIA is fifty dollars (\$50). The annual fee for a clinical laboratory subject to registration under paragraph (2) of subdivision (a) of Section 1265 and performing only provider-performed microscopy, as defined under CLIA is seventy-five dollars (\$75). A clinical laboratory performing both waived and provider-performed microscopy shall pay an annual registration fee of seventy-five dollars (\$75).

(r) The costs of the department in conducting a complaint investigation, imposing sanctions, or conducting a hearing under this chapter shall be paid by the clinical laboratory. The fee shall be no greater than the fee the laboratory would pay under CLIA for the same type of activities and shall not be payable if the clinical laboratory would not be required to pay those fees under CLIA.

(s) The state, a district, city, county, city and county, or other political subdivision, or any public officer or body, shall be subject to the payment of fees established pursuant to this chapter or regulations adopted thereunder.

(t) In addition to the payment of registration or licensure fees, a clinical laboratory located outside the State of California shall reimburse the department for travel and per diem to perform any necessary onsite



inspections at the clinical laboratory in order to ensure compliance with this chapter.

(u) Whenever a clinical laboratory has paid registration or compliance fees, or both, to HCFA under CLIA for the same period of time for which a license is issued under Section 1265, the fee required for the clinical laboratory license under subdivision (f) or (g), and as adjusted pursuant to Section 100450 of the Health and Safety Code, shall be reduced by the percentage of the total of all CLIA registration and compliance fees paid to HCFA by all California laboratories that are made available to the department to carry out its functions as a CLIA agent in the federal fiscal year immediately prior to when the license fee is due.



Approved _____, 1999

Governor

